

## P-19-0009

Chemical Name:

CASRN:

ASSIGNMENTS	NAME	DATE
SAT Chair	William Irwin	SAT Date 11-2-18
HH Hazard Assessor (A)	Keith Jacobs	SAT Date 11-2-18
HH Hazard QC Reviewer (A)	Susan Laessig	12/3/2018
HH Risk Assessor FOCUS (B)	Keith Jacobs	12/10/18
HH Risk QC Reviewer (B)	Sailesh Surapureddi	12/10/2018

Human Health Report Status:		DATE COMPLETED
X	HAZARD DRAFT- Pending Review	11-14-18
X	HAZARD REVIEWED	12/3/2018
X	HAZARD FINAL	12/3/2018
x	RISK DRAFT- pending review	12/10/18
x	RISK REVIEWED	
x	RISK-FOCUS FINAL- Uploaded	12/10/18
	POST-FOCUS UPDATE DRAFT	
	POST-FOCUS UPDATE FINAL- Uploaded	

# 1 HUMAN HEALTH SUMMARY

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EPA estimated the human health hazard of this chemical substance based on its estimated physical/chemical properties, by comparing it to structurally analogous chemical substances for which there are information on human health hazard, and other structural information.

Based on the hazard determination and available quantitative and qualitative risk information, EPA did not identify risks for the PMN substance.

## 1.1 Hazard Summary

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### 1.1.1 Absorption / Metabolism

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- Absorption is expected to be NIL all routes for the parent polymer and NIL to poor all routes for the low molecular weight fractions (p-chem).

### 1.1.2 Structural Alerts

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- Poly-amines for cationic binding

### 1.1.3 Hazard Concerns

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- Concern for polycationic binding to lung membranes and irritation based on poly-amines.

### 1.1.4 Hazard Summary (narrative)

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EPA estimated the human health hazard of this chemical substance based on its estimated physical/chemical properties, by comparing it to structurally analogous chemical substances for which there are information on human health hazard, and other structural information. Absorption is expected to be NIL all routes for the parent polymer and NIL to poor all routes for the low molecular weight fractions (p-chem). EPA identified polycationic binding to lung membranes and irritation based on poly-amines as hazards for the new chemical substance. EPA quantitatively assessed the PMN substance using analog data for surfactants. An inhalation LOAEC of 1.6 mg/m<sup>3</sup> for lung toxicity was used to derive exposure route- and population-specific points of departure for quantitative risk assessment of P-19-0009. A benchmark MOE of 1000 was used to account for LOAEC to NOAEC extrapolation and both interspecies and intraspecies variability/uncertainty.

## 1.2 Exposure and Risk Summary

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Risks to human health for the new chemical substances were evaluated using the points of departure (i.e., LOAEC) described above. For this assessment, EPA assessed worker exposure via dermal exposure and inhalation exposures were estimated to be negligible.

Risks were evaluated for general population exposure to drinking water but not for lung effects via inhalation exposure because there are no releases to air based on information provided by the submitter. Consumer risks were not evaluated because consumer uses were not identified as conditions of use.

### 1.2.1 Workers

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- Although the chemical structure structural alerts indicate that the PMN substance could result in lung cationic binding and irritation, risks were not identified for workers via inhalation because inhalation exposures are estimated to be negligible.
- Irritation hazards to workers via dermal contact were identified based on the presence of amines. Risks for these endpoints were not quantified due to a lack of dose-response for these hazards. However, exposures can be mitigated by the use of appropriate personal protective equipment (PPE), including impervious gloves and eye protection. EPA expects that workers will use appropriate PPE consistent with the Safety Data Sheet prepared by the new chemical submitter, in a manner adequate to protect them. Therefore, EPA does not expect unreasonable risk for the irritation endpoint.

### 1.2.2 General Population

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- Irritation hazard was identified, however effects via drinking water exposure are not expected via this route of exposure due to very low concentrations expected.
- Risks were not assessed for the general population via inhalation exposures since exposures were expected to be negligible.

### 1.2.3 Consumers

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- Risks to consumers were not evaluated because consumer uses were not identified as conditions of use

## 1.3 Potentially Useful Information:

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### 1.3.1 Assumptions and Uncertainties

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Absorption of the PMN is based on p-chem properties

There are no measured data on the PMN substance itself.

Health effects are based on analogue data/structure.

### 1.3.2 Potentially Useful Information

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Potentially useful information would inform understanding of:

Pulmonary effects

Skin irritation

## 2 HUMAN HEALTH HAZARD- PART A

### 2.1 Chemistry Summary

PMN:	Submitter		CRSS Date:	
P-19-0009	Allnex USA Inc.		Nov 1, 2018	
Max. PV (Kg):	Binding Option Marked:		Manu. Import	
	false		<input type="checkbox"/> <input checked="" type="checkbox"/>	
MW:	% <500:	% <1000:	CASNO:	
3,129.00	1.20	5.70		
Structure:			Meas. Est.	
			MP	
			BP	
			Pres.	
			VP	
			S-H2O	Disperible
			Log P	
Chemical Name:			Analogs:	
Use:				
Corrosion protection additive in resin for cathodic electrodeposition dip coating for metal substrates. Amine FGEW = 777 by charge, 782 by termination. Formaldehyde FGEW = 981 by charge, 1565 by termination. Combined FGEW = 434 by charge, 521 by termination. Analogue				

## 2.1 SAT Summary

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### 2.1.1 Absorption

Absorption is expected to be NIL all routes for the parent polymer and NIL to poor all routes for the low molecular weight fractions (p-chem).

### 2.1.2 SAT Health Summary

There is concern for poly-cationic binding to lung membranes.

### 2.1.3 Exposure Routes of Interest

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Route of Interest	
X	Inhalation:
X	Dermal:
X	Ingestion:

## 2.2 Toxicity Data

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### 2.2.1 PMN Data (study summary, POD, same-as)

No data available

### 2.2.2 Analogue/Metabolite Data (chemical, structure, study summary, POD)

No data available

### 2.2.3 SDS Data (composition, hazard identification, toxicological information)

not relevant to PMN substance

### 2.2.4 Other Information

There is additionally hazard for irritation based on amine FGEW < 1000.

## 2.3 Human Health Category (From US EPA 2010 document)

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Chemical Category: not applicable

## 2.4 Point of Departure Selected and Basis

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### 2.4.1 POD for Lung Cationic Binding

POD type (NOAEL/LOAEL): LOAEC

POD Chemical: Polyhexamethylene guanidine phosphate

POD Route: Inhalation

POD Endpoint: Inflammation, metaplasia and fibrosis

POD Value: 1.6 mg/m<sup>3</sup>

POD Basis: Four week study on polyhexamethylene guanidine phosphate in Sprague Dawley rats (sex not reported), 6 hours/day, 5 days/week with a 2 day recovery period.

POD Benchmark MOE: 1,000 (10 for LOAEC to NOAEC \* 10 interspecies UF \* 10 intraspecies UF)

**Reference:** Park, S., et al. (2014). "Humidifier disinfectant-associated interstitial lung disease in an animal model induced by polyhexamethylene guanidine aerosol." American journal of respiratory and critical care medicine 190(6): 706-708.

### 3 HUMAN HEALTH RISK (PART B)

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#### 3.1 USES and EXPOSURES

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##### 3.1.1 Uses

Corrosion protection additive in resin for cathodic electrodeposition dip coating for metal substrates.

##### 3.1.2 Worker Exposure

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###### 3.1.2.1 Inhalation

negligible (VP < 0.001 torr); inhalation exposure is not expected

###### 3.1.2.2 Dermal

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##### 3.1.3 General Population Exposure:

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###### 3.1.3.1 Drinking Water

Drinking water ingestion with ADR as high as ██████████

###### 3.1.3.2 Fish

negligible

###### 3.1.3.3 Air/Inhalation

negligible

##### 3.1.4 Consumer Exposure

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No identified consumer exposures

#### 3.2 RISK CALCULATIONS

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No oral POD for irritation

##### 3.2.1 Worker Calculations

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Risks were not assessed. Inhalation exposures were negligible and only irritation concerns for dermal exposure.

##### 3.2.2 General Population Calculations

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Risks were not assessed. Irritation hazards not expected at the very low exposure concentrations estimated. Inhalation exposures were below modeling thresholds.

##### 3.2.3 Consumer Calculations

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Risks to consumers were not evaluated because consumer uses were not identified as conditions of use